

PATENT COOPERATION TREATY

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
GAL EHRLICH
PRTSI, INC.
P.O. BOX 16446
ARLINGTON, VA 22215

PCT

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing (day/month/year)	16 AUG 2007
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Applicant's or agent's file reference

31253

IMPORTANT NOTIFICATION

International application No.

PCT/IL06/00075

International filing date (day/month/year)

18 January 2006 (18.01.2006)

Priority date (day/month/year)

15 February 2005 (15.02.2005)

Applicant

NEW LEAF CAPITAL LTD.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/ US

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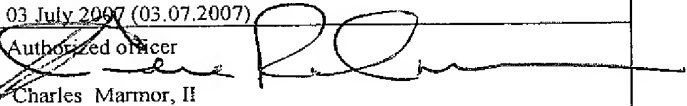
PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 31253	FOR FURTHER ACTION	See Form PCT/IPEA/416																								
International application No. PCT/IL06/00075	International filing date (day/month/year) 18 January 2006 (18.01.2006)	Priority date (day/month/year) 15 February 2005 (15.02.2005)																								
International Patent Classification (IPC) or national classification and IPC IPC: A61B 5/02(2006.01) USPC: 600/504,506																										
Applicant NEW LEAF CAPITAL LTD.																										
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																										
<p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>			<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input checked="" type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand 11 September 2006 (11.09.2006)		Date of completion of this report 03 July 2007 (03.07.2007)																								
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer  Charles Marmor, II Telephone No. (571) 272-3000																								

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished
- ☒ the description:
pages 1-34 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☒ the claims:
pages 35-47 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☒ the drawings:
pages 1-20 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IL06/00075**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>2,3,5,6,8-10,16-23,28-31,33-36,39,40,42-89</u>	YES
	Claims <u>1,4,7,11-15,24-27,32,37,38,41</u>	NO
Inventive Step (IS)	Claims <u>2,3,5,6,8-10,16-23,28-31,33-36,39,40,42-89</u>	YES
	Claims <u>1,4,7,11-15,24-27,32,37,38,41</u>	NO
Industrial Applicability (IA)	Claims <u>1-89</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and Explanations (Rule 70.7)

Claims 1, 4, and 41 lack novelty under PCT Article 33(2) as being anticipated by US Patent No. 4,803,431 to Sano et al. Sano teaches a method of calculating blood flow (a three-dimensional velocity of the blood flow) in an organ (vein) of a subject using output radiofrequency signals transmitted to the organ and input radiofrequency signals received from the organ. A phase shift is determined of the input signals relative to the output signals and the phase shift is used to calculate the blood flow (col. 4, lines 13-44; col. 5, lines 6-37 of Sano). Regarding claim 4, Sano also teaches a signal processing unit and calculator 206 for executing the method described above (col. 4, lines 40-43 of Sano).

Claims 7, 11-15, 24-27, 32, 37, and 38 lack novelty under PCT Article 33(2) as being anticipated by US Patent No. 5,642,734 to Ruben et al. Ruben teaches a system comprising a radiofrequency generator 34 for generating output radiofrequency signals (col. 5, lines 20-30 of Ruben). A plurality of electrodes 48A, B 50A, B are designed to be connectable to the skin of the subject and transmit output radiofrequency signals to the organ and sense input radiofrequency signals of the organ (figs. 5A & B; col. 5, lines 45-64 of Ruben). A signal processing unit 34, 42, 94 determines a phase shift of the input signals relative to the output signals (col. 9, lines 34-41 of Ruben), the phase shift being indicative of the blood flow in the organ, wherein such a relationship between the phase shift and blood flow is an inherent property of the phase shift and blood flow. Regarding claim 11, a mixer electrically communicates with the generator and some of the electrodes and mixes the output signals and input signals to provide a mixed radiofrequency signal indicative of the blood flow and electronic circuitry for filtering out a portion of the mixed signal (col. 7, lines 3-17; col. 7, line 51-col. 8, line 37 of Ruben).

Regarding claim 12, the mixer is operable to provide a radiofrequency sum and a radiofrequency difference (col. 7, lines 51-62; col. 8, lines 20-31 of Ruben).

Regarding claim 13, the circuitry comprises a low pass filter 128 for filtering out the sum (col. 8, lines 32-37 of Ruben).

Regarding claim 14, the circuitry comprises an analog amplification circuit (col. 6, lines 10-39 of Ruben), wherein the circuit is certainly capable of amplifying any signal. Applicants should note that "for amplifying . . ." is merely "intended use" language.

Regarding claim 15, the circuitry comprises a digitizer 120, wherein the digitizer is capable of digitizing any radiofrequency signal (col. 7, lines 22-23 of Ruben). Applicants should note that "for digitizing . . ." is merely "intended use" language.

Regarding claim 24, the language in this claim appears to merely describe a method step describing a step of selecting the number of electrodes, wherein such a method limitation fails to further limit the apparatus of claim 11. At best, the language may be considered "product by process" language wherein the claim is evaluated based on the result of such a step rather than the accomplishment of the step itself. In such a case, the end result of such a step and the invention of Ruben are the same.

Regarding claims 25-27, the plurality of electrodes comprises two, three, or four electrodes (figs. 5A, B of Ruben).

Regarding claim 32, a detector electrically communicates with at least a portion of the electrodes for detecting a voltage between a first and second location of the subject and for generating the input signals in response to the voltage, wherein the input signals are indicative of impedance (col. 5, line 45-col. 6, line 47 of Ruben).

Regarding claims 37 and 38, the system comprises a display device, wherein a personal computer generally refers to the system built around a microprocessor for personal use, including the input/output devices and peripherals that a general user would require, wherein such device include a display. With further regard to claim 38, a general display for a personal computer is certainly capable of displaying the blood flow as a function of time.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/IL06/00075

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claims 28 and 29 are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof:

On line 2 of claim 28, "to so as to" should be replaced with "so as to".

On line 3 of claim 29, "to wind" should be replaced with "to wind about".

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Claims 2, 3, 5, 6, 42, and 43 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method or apparatus wherein calculating the blood flow comprises using a linear relationship between the phase shift and blood flow, in combination with all of the other limitations of the claims.

Claims 8-10 and 76-89 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a system wherein the signal processing unit comprises an envelope elimination unit designed and configured to reduce or eliminate amplitude modulation of the input radiofrequency signals so as to provide input radiofrequency signals of substantially constant envelope, in combination with all of the other limitations of the claims.

Claims 16 and 17 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a system wherein the circuitry is designed so as to minimize the sensitivity of the input radiofrequency signals to impedance differences between the plurality of electrodes and the organ of the subject, in combination with all of the other limitations of the claims.

Claims 18-23 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a system wherein a data processor calculates at least one quantity using the remaining portion of the mixed radiofrequency signal, said at least one quantity being selected from the group consisting of a stroke volume, cardiac output, brain intraluminal blood flow, and artery blood flow rate, in combination with all of the other limitations of the claims.

Claims 28-31 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a system wherein at least a portion of the electrodes is designed and constructed so as to have a substantial constant sensitivity to electrical signals transmitted

Supplemental Box

through the electrodes, irrespective of an orientation of the electrodes on the subject, or the electrodes comprises at least one elongated conducting material designed and constructed to wind about at least a portion of an external organ of the subject, so as to have a substantial constant sensitivity to electrical signals transmitted through said electrodes, irrespective of an orientation of the electrodes on the organ, in combination with all of the other limitations of the claims.

Claims 33-36 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a system further comprising at least one sensor for sensing the voltage, said at least one sensor being designed and constructed for generating signals having a magnitude which is a function of blood flow in, from, or around the organ, or wherein the electronic circuitry comprises a differentiator for performing at least one time-differentiation, to provide a respective derivative of the impedance and/or hemodynamic reactance of the organ, in combination with all of the other limitations of the claims.

Claims 39 and 40 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a system wherein the signal to noise ratio increased by at least 10 dB or at least 20 dB, in combination with all of the other limitations of the claims. .

Claims 44-46 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method further comprising reducing or eliminating amplitude modulation of the input radiofrequency signals so as to provide input radiofrequency signal of substantially constant envelope, in combination with all of the other limitations of the claims

Claims 47-75 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method further comprising mixing the output radiofrequency signals and said input radiofrequency signals so as to provide a mixed radiofrequency signal being indicative of the blood flow, and filtering out a portion of the mixed radiofrequency signal so as to substantially increase a signal to noise ratio of a remaining portion of the mixed radiofrequency signal, in combination with all of the other limitations of the claims.

Claims 1-89 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.